UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,270	09/24/2001	Gerd Geisslinger	016915-0244	2372

7590 10/30/2003

Richard L Schwaab
Foley & Lardner
Washington Harbour
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,270	Applicant(s) GEISSLINGER ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response and amendment filed August 7, 2003 are acknowledged. Applicant's amendment is persuasive to remove the rejections under 35 USC 101, 112 and 102 over the Bang reference.

Applicant has also requested that claim 20 be addressed since it was not addressed in the previous office action. Note that the limitations of claim 20 was addressed in the 103 rejecton, since weight percentages of R and S enantiomers were only recited in claim 20, however the Examiner had not included this claim in the rejection line. Please note that applicant has cancelled claim 20, see pages 3 and 4 of the Response.

Claim Objections

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note that the base claim 21 does comprise a medicament, i.e., an arylpropionic acid derivative. Therefore claim 25 does not further limit the base claim.

Claim Rejections - 35 USC § 102

Claims 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisslinger et al. (USPN 5,200,198).

Geisslinger et al. (USPN 5,200,198) discloses an oral dosage form of tablets, dragees and gelatin capsule effective in treating diseases characterized by pain or inflammation comprising 75 or 100 mg. of 99.5% pure R-flubiprofen, pharmaceutical adjuvants and carriers, see col. 7 line

54 to col. 8 line 3, see col. 5, lines 3-10. Geisslinger et al. further teaches the particular salts recited herein, i.e., salts of alkali metals, alkaline earth metals, ammonium and amino acid salts, in particular lysinate, see claims 1-9 in particular. Geisslinger et al. teaches that the medicament comprises retarding additives, see claim 10 for example. Geisslinger finally teaches a dosage form comprising a rapidly and retardedly inflowing form, see claims 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisslinger et al. (USPN 5,200,198).

Geisslinger et al. (USPN 5,200,198) discloses a discloses an oral dosage form of tablets, dragees and gelatin capsule effective in treating diseases characterized by pain or inflammation comprising 75 or 100 mg. of 99.5% pure R-flubiprofen, pharmaceutical adjuvants and carriers, see col. 7 line 54 to col. 8 line 3. Geisslinger et al. further teaches the particular salts recited

herein, i.e., salts of alkali metals, alkaline earth metals, ammonium and amino acid salts, in particulat lysinate, see claims 1-9 in particular. Geisslinger et al. finally teaches that the medicament comprises retarding additives, see claim 10 for example. Geisslinger et al. also teaches a medicament comprising from about 95%:5% to about 60%:40% of R-flubiprofen: S-flubiprofen. Geisslinger et al. also teaches that each unit dosage form can contain from 10 to 100 mg of the enantiomer mixture, see cols. 7-8 and claim 3 in particular. Geisslinger finally teaches a dosage form comprising a rapidly and retardedly inflowing form, see claims 10-11.

Geisslinger et al. does not particularly teach the diseases herein.

Berkow et al. teaches that rheumatic diseases, asthma, inflammatory intestinal disease such as colitis and Crohn's disease, arteriosclerosis, and some immune diseases are known to be caused by iflamaation and accompanied by pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ R-flubiprofen in treating any disease associated with pain and inflammation.

One of ordinary skill in the art would have been motivated to employ R-flubiprofen in treating any disease associated with pain and inflammation because the prior art broadly teaches that R-flubiprofen is useful in treating any disease associated with pain and inflammation and all diseases herein are known to be associated with both pain and inflammation.

Response to Arguments

Applicant's arguments filed August 7, 2003 have been fully considered but they are not persuasive. Applicant argues that the Geisslinger reference does not teach the treatment of diseases induced by the action of NF-KB. Note that applicant is constructively arguing that the

mechanism of action, i.e., NF-KB action is not taught in the prior art reference. Note that the elucidation of a mechanism of action does not patentably distinguish the instant claims over the prior art. Note that the ultimate goal of the instant claims and that of the prior art are indistinguishable, they both treat diseases that are associated with pain and/or inflammation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
October 17, 2003

THEODORE J. CHIARES
PRIMARY EXAMINER
GROUP ~~1200~~ 1617